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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,725	01/27/2006	Hideki Tanji	10921.0296USWO	9962

52835 7590 08/31/2009

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EXAMINER	
TURK, NEIL N	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,725	TANJI, HIDEKI	
	Examiner	Art Unit	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009 and 30 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on June 22nd, 2009 and July 30th, 2009. Claims 1-13 are pending. Claims 14-18 have been cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22nd, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recited "wavelength determination step" of claim 1 is unclearly recited. Claim 1 recites, in part, "...a wavelength determination step of determining a relationship between variations of response and variations of

wavelength with respect to a reference board whose response varies continuously as the wavelength of light irradiated onto the reference board varies, the variations of the wavelength of irradiated light being caused by environmental temperature changes that also cause fluctuations of response." First, what sort of "response" is given by the reference board? What sort of value is this? Additionally, the step calls for a wavelength determination, but the recitation provides for "determining a relationship between variations of response and variations of wavelength..." It is thereby unclear how a wavelength is determined. Does Applicant intend to claim a step in which a corrected wavelength value is determined as a result of irradiating light onto a reference board? Does Applicant intend the final result of such a step to come to a conclusion on a certain numerical wavelength that should be used for further calculations down the line in the actual assay that will follow? As currently recited, the step is unclear in how a wavelength is determined and does not establish how once such a relationship is found, the relationship is then used to output the final, corrected wavelength. The step as currently recited appears to merely recite functionalities of a reference board and does not provide for determining a corrected wavelength.

Further, the calculation step of claim 1 is unclear in constitution with the above step. It is unclear what is meant by, "...a calculation step of calculating a concentration of a specific component in the sample liquid based on the predetermined relationship between variations of response and variations of wavelength with respect to the reference board." First, there is no antecedent basis for the recitation "the predetermined relationship"? Does Applicant intend to recite that the calculation step is

based on the wavelength determined in the determination step (in which such a resultant wavelength has been determined as a result of the relationship between variations of response and variations of wavelength with respect to a reference board)? From Applicant's remarks it appears that before undergoing the analyzing method to find a concentration of a specific component, one must find a corrected or "true" wavelength to use in the calculation down the line. Thereby, it would appear that in the calculation step, the determined wavelength (a single quantified wavelength) from the step of "a wavelength determination step" would be used for calculating the concentration of the specific component.

Additionally, it is unclear what purpose the first detection step and second detection step have in the analyzing method. The first and second detection steps are not utilized in the wavelength determination step or the calculation step and it is thereby unclear how they are incorporated into the method. Is the calculation step based off of the wavelength determination step, first detection step, and second detection step? Is the second detection step, which relates to the reference board, somehow tied in with the wavelength determination step?

Clarification is required.

Claim 1 recites the limitation "the predetermined relationship". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Matzinger (5,780,304).

Matzinger discloses a method and apparatus for analyte detection having an on-strip standard. Matzinger discloses that the invention relates to a test device and method for optically measuring the concentration of glucose in whole blood (lines 8-12, col. 1). Matzinger discloses a test strip that has a reaction zone (with color-producing reagent), which varies in reflectance as a function of the quantity of analyte present, and a standard zone that is positioned so as to lead the reaction zone as the strip is inserted into a reading apparatus. Matzinger discloses that the apparatus has optical means for sequentially determining the reflectance value of the standard zone and for determining the reflectance value of the reaction zone after the strip has been inserted. The apparatus further includes means for calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4; lines 61-67, col. 8; lines 1-31, col. 9). Matzinger discloses the apparatus 12 is provided with a power switch 20 for activating the apparatus and the optics block 32 (including LED 36; irradiator) is affixed to the apparatus and operable to direct light through aperture 30 in rapid bursts, "chops", for a period of time each time it is activated

(lines 50-67, col. 5; lines 19-35, col. 6, figs. 1-3). Matzinger discloses that the standard zone 60 provides a calibrated standard reflectance value against which the reflectance of the color-developed reaction zone may be measured so as to allow computation and reporting of the presence or quantity of the analyte, which is detected by a photodetector 38 (detecting unit), which in turn communicates with converters and finally the microprocessor 33 (calculator and storage said to be therein) (lines 40-67, col. 9; lines 1-21, col. 10; lines 6-28, col. 11; figs. 1, 4, and 6). Matzinger also discloses that the reflectance of the surface presented to the optics is measured at all the various positions and multiple readings are taken at each position in spaced periods of time (lines 30-67, col. 11, figs. 7-11). Matzinger further discloses that the apparatus views the gray target and read a value for its reflectance at each LED wavelength and compare the values to the factory stored values for the gray reading. If there is a difference between the stored readings and the actual readings an adjustment is made (lines 36-50, col. 6; lines 5-67, col. 13). Matzinger discloses further calibration measures and checks throughout column 14. Matzinger also discloses that the microprocessor employs a look-up table to provide proper coefficients for calibration of the specific test strip employed in the apparatus to correct K/S ratio (lines 1-60, col. 15). Examiner interprets the function of the microprocessor 33 (storage and calculator therein) to check and compare the gray readings against factory-stored values for adjustments to correspond to the selector and calculation corrections as claimed.

Response to Arguments

Applicant's arguments, see pages 6-10, filed July 30th, 2009, with respect to claims 6-13 rejected under 35 USC 112, 2nd paragraph have been fully considered and are persuasive. The rejection of claims 6-13 under 35 USC 112, 2nd paragraph has been withdrawn. Examiner notes that independent claim 6 is drawn to an apparatus and its constituent parts, which have been recited with various functionalities/processes. Whereas the claim does not lack definiteness under 35 USC 112, 2nd paragraph, Examiner notes that as the claims are drawn to an apparatus, prior art which discloses all of the positively recited structural limitations (a storage, a light irradiator, a detecting unit, and a calculator) will be said to be capable of the recited functionalities/process recited in the claim.

With regards to claims 1-5 rejected under 35 USC 112, 2nd paragraph, Applicant traverses the rejection. Applicant's arguments are not persuasive. In view of Applicant's amendments to the claims, the claims remain rejected under 35 USC 112, 2nd paragraph, as discussed above. Examiner asserts that the claim is unclear in providing a wavelength determination step as the recitation only points to properties of a reference board and does not provide to determine a wavelength. Further, as discussed above, it is unclear how the first and second detection steps relate in the method, and namely, the calculation step of the method. Clarification is required.

With regards to claims 1-5 rejected under 35 USC 102(b) as being anticipated by Matzinger, Applicant traverses the rejection. In view of Applicant's amendments to the claims, the rejection of claims 1-5 under 35 USC 102(b) over Matzinger has been removed.

With regards to claims 6-13 rejected under 35 USC 102(b) as being anticipated by Matzinger, Applicant traverses the rejection. Applicant argues that claim 6 requires a storage for storing a relationship between variations of response and variations of wavelength with respect to a reference board whose response varies continuously as the wavelength of light irradiated onto the reference board varies, variations of the wavelength of irradiated light being caused by environmental temperature changes that also cause fluctuations of response. Applicant argues that Matzinger does not disclose or suggest these features. Examiner argues that as claim 6 is directed to an apparatus, such process/functional limitations are not afforded patentable weight. This is such as Applicant must patentably distinguish the claims over the prior art in terms of structure and not in terms of processes/functions, as the claims are drawn to an apparatus. As Matzinger discloses all of the positively recited structural elements of the claim, the device of Matzinger is said to be capable of all such functionalities/processes in claim 7. Specifically, Applicant has claimed a storage. Matzinger discloses a microprocessor, which Examiner interprets to include both the calculator and storage components as would be well known to be implicitly included in a microprocessor. As Matzinger disclsoes a storage (i.e. a memory), and a memory is capable of storing data/instructions, including ones that relate to a relationship between variations of

response and variations of wavelength as recited in claim 6. The relationship is not a positively claimed element of the device, but is merely drawn to a capability of a storage to be able to store a piece of data.

As there is no such deficiency in Matzinger with respect to claim 6, dependent claims 7-13 are maintained rejected as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Sean E Conley/
Primary Examiner, Art Unit 1797